pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION
Bureau of Radiation Protection

April 21, 2010

The Honorable Edward J. Markey, Chairman
Subcommittee on Energy and Environment
111th Congress of the United States
U.S. House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6155

Re: Pennsylvania's Oversight of the Treatment of Patients with Radioisotopes

Dear Chairman Markey:

This letter is in response to your request for information regarding Pennsylvania's regulation of medical patients being treated and released with medical isotopes. Detailed responses to the questions contained in your letter are provided in the enclosure. Please note that the Commonwealth of Pennsylvania rules relating to radiation protection can be found on our Web site at www.pacode.com, Title 25, Article V, Radiological Health. Pennsylvania entered into agreement for the regulation of certain radioactive materials with the U.S. Nuclear Regulatory Commission (NRC) on March 31, 2008. As recently as January 26, 2010, our program has been found to be adequate and compatible with the NRC to protect public health and safety in Pennsylvania.

The authority to regulate the safe use of radiation in Pennsylvania is with the Bureau of Radiation Protection (BRP), which is part of the Pennsylvania Department of Environmental Protection (DEP). The BRP oversees the regulation of radioactive materials licensees, registration and use of X-ray devices, radon, low-level waste, and decommissioning sites throughout the Commonwealth. The BRP mission is to ensure that public and occupational exposure to radiation from man-made and controllable natural sources, and any corresponding impact on the environment, is as low as reasonably achievable (ALARA).

If you need additional information or need further clarification, please do not hesitate to contact Mr. Joseph Melnic, Manager for the Radiation Control Division, by e-mail at jmelnic@state.pa.us or by telephone at 717.787.2480. Thank you for your letter and concerns for public health and safety.

Sincerely,

David J. Allard, CHP
Director
Bureau of Radiation Protection

Enclosures

Question 1:
How many iodine-131 (I-131) licensee facilities are overseen by your State?

Response 1:
We have 106 licensees that are authorized to use iodine-131 in therapeutic quantities (i.e., quantities that exceed 30 microcuries, which require a written directive).

Question 2:
How often does your State perform sampling inspections at each of these I-131 licensee facilities?

Response 2:
Pennsylvania inspects its medical licensees that administer therapeutic doses of I-131 every three years. Inspection frequencies are based upon the type and scope of the licensee's program. The medical licensees that administer therapeutic doses of I-131, referred to as a "Medical Institution - Written Directive Required," require an inspection frequency of once every three years.

Question 3:
What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.

Response 3:
Pennsylvania follows NRC applicable guidance outlined in Inspection Manual Chapter 2800 (IMC 2800), enclosed. Medical licensees that administer therapeutic doses of I-131 are inspected every two to three years. Typically, large medical institutes and university-run medical facilities hold "Medical Institution Broad Scope" licenses. These licenses require an inspection frequency of once every two years. Another type of medical license that administers therapeutic doses of I-131, referred to as a "Medical Institution - Written Directive Required," requires an inspection frequency of once every three years.

Question 4:
NCRP 155, includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients." For a patient receiving 175 millicuries of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towel; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?

Response 4:
Pennsylvania's dose limits and restrictions are required to be compatible with the NRC's criteria. We have incorporated by reference the regulatory requirement in 10 CFR 35.75. Our inspectors

Question 7:
In the past ten years, how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.

Response 7:
Since becoming an AS on March 31, 2008, Pennsylvania has not found any cases in which a required dose calculation was not performed by the licensee or the licensee did not provide written instructions to the patient on how to maintain doses to other individuals ALARA.

Question 8:
In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?

Response 8:
Pennsylvania believes that a licensee is capable of calculating conservative dose estimates for members of the public using reasonable assumptions concerning occupancy, building geometry, and other factors.

Question 9:
Has your State ever attempted to determine how many patients treated with I-131 are: a) sent home, b) sent to a hotel, or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?

Response 9:
Pennsylvania does not maintain records regarding the destinations of released patients from medical institutions. Instead, during onsite inspections at medical facilities, inspectors review a representative sample of cases involving therapeutic uses of radioactive materials to determine from patient records the circumstances whereupon the patient was released and the content of the counseling the patient received. These reviews are used to verify compliance with the regulations regardless of the patient's final destination.

Question 10:
In patients with doses in excess of the default limits, has your State ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has your State ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.

Response 10:
As discussed in responses above, Pennsylvania inspectors evaluate the licensee's program for patient release to verify compliance with Pennsylvania requirements. Included in this evaluation

Question 15:

Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.

Response 15:

We have no such documentation. If licensee documents were required, and are found to be missing or incomplete, then it is considered to be a violation of Pennsylvania regulations and would be identified and cited as such by inspectors.

DRAFT DOCUMENT

DEP INSPECTION MANUAL

MANUAL CHAPTER 2800

MATERIALS INSPECTION PROGRAM

2800-01 PURPOSE

To establish the inspection program for licensees authorized to possess, use, transfer, and dispose of radioactive material associated with various types of use, i.e., industrial, academic, research and development, manufacturing, distribution, irradiators, well logging, industrial radiography, medical programs, various types of service (i.e., leak testing of sealed sources, calibration of instruments, servicing of devices, collection and repackaging of radioactive waste for final disposal), and transportation related thereto.

2800-02 OBJECTIVES

02.01 To establish the general policy for the materials inspection programs.

02.02 To describe a performance-based inspection approach and to identify specific conditions of poor performance which require the licensee to be inspected more frequently.

02.03 To place the major emphasis of the materials inspection program on timely and thorough follow-up of incidents and events.

02.04 To continue and enhance risk-informed, relative priorities for routine inspections of all licensees.

02.05 To aid in the achievement of a consistent process of inspection for materials licensees.

2800-03 DEFINITIONS

03.01 Initial Inspection. The first inspection after a license is issued to a licensee.

03.02 Inspection. The act of assessing licensee performance to determine whether the licensee is using radioactive material safely and whether an individual or organization is in compliance with established standards, such as regulations, license conditions, and the licensee commitments submitted in support of a license (and incorporated by "tie-down" conditions). Inspections involve a visit to a licensee's facility and/or temporary jobsite by Department of Environmental Protection (DEP) inspector(s), observations of licensed activities, interaction with licensee personnel, and transmission of the inspection findings. Pre-licensing visits and telephone contacts are not considered inspections.

2800-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Central Office Director, Bureau of Radiation Protection. Provides overall program direction for the DEP materials inspection program.

04.02 Regional Radiation Protection Supervisor. Oversees implementation of the materials inspection program within their respective region.

04.03 Central Office Chief, Division of Radiation Control

a. Develops and directs the implementation of policies, programs, and procedures for inspecting applicants, licensees, and other entities subject to DEP jurisdiction.

b. Assesses the effectiveness, uniformity, and completeness of implementation of the materials inspection program.

c. Approves changes to the materials inspection program.

d. Ensures that operating plans are consistent among the Regions responsible for materials inspections.

04.04 Regional Radiation Protection Program Manager

a. Manages the implementation of the inspection program elements performed in a Regional Office.

b. Ensures, within budget limitations, that the Regional Office staff includes adequate numbers of inspectors to carry out the inspection program described in this chapter, including that which may be needed for reactive inspections.

c. Applies inspection resources, as necessary, to deal with significant issues and problems at specific facilities.

d. Coordinates, with Central Office, to obtain technical assistance, as necessary.

e. Recommends changes to the materials inspection program to the Central Office Chief, Division of Radiation Control.

04.05 Regional Radiation Protection Supervisor(s)

a. Proposes changes to the materials inspection program.

b. Implements the Regional materials inspection program.

c. Reviews and approves inspection schedules.

d. Ensures that Regional inspectors achieve and maintain qualifications.

To adequately prepare, an inspector shall review

1. the license to determine if it has any unusual license conditions that would affect the approach to the inspection, i.e., authorization for an incinerator, authorization for use of material at temporary job sites,

2. the licensee's recent inspection and enforcement history, i.e., results of the last inspection and any outstanding open items and determining whether any events have been reported by the licensee during the current inspection cycle,

3. any commitments made by the licensee or restrictions imposed by DEP as a result of a Confirmatory Action Letter or an Order issued since the last inspection,

4. any notes in the file regarding special inspection emphasis, i.e., license reviewer's note to request a near term inspection regarding a significant licensing action. For example, an amendment for a new medical therapy modality under 10 CFR 35.1000 shall be inspected within 12 months of the date of the amendment [see Section 07.02.b].

It is not necessary for the inspector to review all the current licensing documents and procedures on file. For problems identified during the course of the routine inspection, the inspector should ask the licensee for pertinent procedures and backup licensing documents maintained onsite by the licensee. If the documents are not available from the licensee, the inspector should contact the region for assistance. This practice would apply to routine inspections only.

To prepare for a reactive inspection, the inspector will review specific information for reactive inspections as determined by the inspector and his or her supervisor on a case-by-case basis [see Section 05.02].

Inspectors should anticipate whether or not they will encounter protected information during inspection of a licensee. Inspectors should be aware of minimum handling requirements for sensitive–unclassified information, i.e., Safeguards Information, Official Use Only, and Proprietary Information. For current instructions, contact the Central Office for direction.

The inspector should identify the location of the licensee, make travel arrangements, discuss special aspects of the inspection with his or her supervisor (i.e., inspection of temporary job sites), and obtain the supervisor's approval for the travel itinerary.

Finally, the inspector selects appropriate and calibrated radiation detection instrumentation for the inspection and obtains the necessary inspection forms.

b. Onsite Inspection Activities. Based on the pre-inspection activities, the inspector should be prepared to evaluate a licensee's performance of the licensee's radiation

equipment, or meet any special requirements for entering sterile environments). Observations of licensee operations, interviews with staff, review of licensee documents to complement and support inspector observations, and radiation surveys to obtain independent and confirmatory measurements should then be conducted. Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, overall management of the licensed program, and integration of safety.

The inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to occur or continue in his or her presence in order to provide a basis for enforcement action.

Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with licensed activities. For example, an inspector should not insist on interviews when:

(a) a worker is delayed in performing scheduled work activities (i.e., delayed departure to a temporary job site)
(b) a worker is preparing or administering dosages or doses,
(c) a worker is providing patient care, or
(d) a licensee is dealing with customers or members of the public.

3. Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of "historical" records should only occur if the current records are out of compliance and the inspector believes it necessary to determine the presence of a prevalent or persistent problem. If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies, while onsite, of all records that are needed to support the apparent violation. The inspector should be aware whether or not the information reviewed or gathered has been declared as proprietary information by the licensee.

   In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete.

   Inspectors shall ensure that the licensee understands that the retained record will become publicly available, and shall give the licensee the opportunity to provide redacted copies or to request withholding the information pursuant.

4. The inspector should advise the licensee of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management. The inspector should allow ample time during the inspection for a licensee to correlate information about

licensee management's awareness of the radiation protection program.

When an inspection is likely to involve proprietary information, given the technical area or other considerations of inspection scope, the inspector should discuss with licensee management during the entrance meeting how the information will be handled during the inspection.

(b) Follow up on Previous Items. Determine whether the licensee followed up on cited violations identified during the previous inspection. Determine whether the licensee took the corrective actions as described in its response to the NOV and followed-up on safety concerns and unresolved issues identified during the previous inspection.

(c) General Overview. The inspector should understand the current organization for radiation safety at the facility and the size of the current and anticipated radiation use program.

(1) Organization. Interview cognizant licensee representatives about the current organization of the program. Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Identify the reporting relationship and management structure between the licensee's executive management, the Radiation Safety Officer (RSO), and, if applicable, the Chairperson and other members of the Radiation Safety Committee (RSC).

(2) Scope of Program. Interview cognizant personnel to determine the types, quantities, and use of byproduct material, frequency of use, staff size, etc., and anticipated changes in the range of the radiation use program. Determine if the licensee possesses material in accordance with a general license.

(d) Observation of Actual Facilities and Licensed Activities. Ideally, the inspector should observe work in progress that involves NRC-regulated activities. If there is no opportunity, then the inspector should ask the workers to demonstrate and explain selected licensed activities. It is of utmost importance to inspect licensed activities at temporary job sites [see Section 07.04].

(1) Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed.

(2) Conduct inspections of licensed operations that are a potentially significant contributor to dose, regardless of

licensee understands the additional requirements, and maintains compliance with the special license conditions.

(g) Exit Meeting. At the conclusion of the inspection the inspector should conduct an exit meeting with the most senior licensee representative present at the facility.

If a senior management representative is unavailable for the exit meeting, the inspector should hold a preliminary exit meeting with appropriate staff onsite. As soon as practical after the inspection, the inspector shall hold an exit meeting directly with a senior management representative (and the licensee's RSO, if not present at the preliminary exit meeting). This meeting involving the licensee's management and RSO will usually be held by telephone conference call.

(1) For initial and routine inspections, the inspector should request the meeting and control the meeting for purposes of the inspection. During the meeting, the inspector shall explain any cited violation of DEP requirements and the inspector's understanding of the licensee's corrective action plan for each violation [See Section 05.01.b.4 about keeping the licensee informed of apparent violations during the inspection].

To avoid the formal disputed violation process [See DEP Enforcement Manual], the inspector should confirm the licensee's agreement and mutual understanding of cited violations and associated corrective action plans. If the licensee disagrees with a violation, the inspector should contact his or her supervisor before leaving the site to obtain further instructions. It may be necessary to continue the inspection or modify the cited violation. Together, the inspector and supervisor should make decisions about the enforcement strategy. Before leaving the site, the inspector should inform the licensee about the next steps in the enforcement process.

The inspector should explain safety-related concerns or unresolved items identified during the inspection, and the status of any previously identified violations.

Prompt corrective action must be initiated by the licensee for safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee facility. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated. If the inspector and the licensee disagree on the magnitude of the concern regarding safe operation of the facility, regional management should be notified immediately.

Although deficiencies identified in some areas (i.e., workers'

Reactive inspections will be performed using the guidance in Inspection Procedure (IP) 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy."

A narrative inspection report will be written for all reactive inspections. The narrative report will include a discussion of the sequence of events leading up to the incident, the contributing and root causes of the event, corrective actions taken or proposed by the licensee, and a discussion of the regulations applying to the incident. The inspector shall annotate inspection reports with the NMED Event No. if the reactive inspection was initiated by an NMED reportable event. Enclosure 3 provides instructions to properly "complete" the record for NMED. Enclosure 5 may be completed to document inspection findings that were unrelated to the event [see Section 08.03.b].

05.03 Initial Inspections: Initial inspections of a new licensee or an existing licensee which obtained an amendment for Program Code 02240 (Medical Therapy–Other Emerging Technology) shall be announced and completed within 12 months of the date the new license or amendment was issued.

a. Initial inspections of all licensees. Once onsite, the inspector should interview licensee staff (management and technical) to determine if licensed material has been possessed or licensed operations have been performed. Methods for determining if licensed activities have been performed include, but are not limited to the following: performing a site tour, performing confirmatory measurements, and/or contacting distributors of radioactive material, such as local radiopharmacies, to see if they have distributed material to the licensee. If the licensee has possessed licensed materials or performed licensed operations, then the inspector should conduct an inspection in accordance with Section 05.01 and other applicable guidance.

   If it is determined that the licensee has not possessed licensed material or performed licensed operations, the inspector should:

   1. Determine the licensee's plans for future possession of licensed material or plans to perform licensed operations. In assessing the licensee's future plans, the inspector should determine if adequate facilities and equipment are in place to safely handle licensed material, as described in the license application.

   2. Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should include a discussion on unique license conditions.

   3. Request that the licensee notify the DEP before receipt of licensed material or initiation of licensed operations.

   4. Document the onsite inspection. The "program scope" description should include the licensee's plans for future possession of material or plans to perform licensed operations.

05.05 Telephonic Contacts (Priority T). For certain licensees, the regions shall use telephone contacts at 5-year intervals in lieu of an onsite inspection, with the exception of initial or reactive inspections. Enclosure 1 designates these licensees as priority T. As defined in Section 2800-03, telephonic contacts are useful for staying in touch with priority T licensees. Procedures for using the telephonic contacts are included as Enclosure 2. A telephonic questionnaire is attached as Enclosure 2, Exhibit 1 and standard responses back to licensees contacted by telephone are included as Enclosures 4 and 5. This questionnaire should be completed, signed by the inspector, and placed in the file, and the "next inspection date" shall be changed to indicate the date of the next telephonic contact. The inspector shall brief the supervisor about the telephonic contact.

2800-06 INSPECTION INTERVALS

06.01 Scheduling Inspections. To achieve the goals of cost saving and efficient use of staff time and travel, inspections (other than initial inspections) may be scheduled within a window around their inspection due date. Inspection of licensees in priorities 1, 2, and 3 may vary around their due date by ± 25 percent. Inspection of priority 5 licensees and telephonic contact of priority T licensees may vary around their due date by ± 1 year. Inspections will not be considered "overdue" until they exceed the scheduling window. Inspections may be scheduled before their window if the inspector receives information that warrants earlier inspection.

06.02 Combining Inspections. If a licensee holds several licenses with different Program Codes that are assigned different Priority Codes in Enclosure 1, a single inspection may be scheduled whenever practicable to aid in more effective use of the inspector's time spent in travel status. In the determination to combine inspections on a continuing basis, consideration should be given to not "over-inspect" a lower-priority license versus the need and desirability to inspect a licensee's total activities for a more complete assessment of its safety and compliance performance. The priority designations of the lower-priority licenses shall not be changed in these cases; the more frequent inspections of lower-priority licenses shall be handled only in the scheduling process.

06.03 Inspections After Escalated Enforcement. If escalated enforcement action has taken place for a particular licensee, a follow-up inspection to focus on significant violation(s) shall be scheduled and conducted within 6 months of the last inspection or sooner, in accordance with the guidance in this MC regarding reduction of inspection interval, after completion of the escalated enforcement action, to assess the licensee's follow-up actions in response to the previous violations. Regions may perform this follow-up inspection as a part of a routine inspection.

06.04 Reduction of Inspection Interval

a. The inspection interval shall not be extended beyond that specified by the priority system indicated in Enclosure 1. The interval between inspections may be reduced (shortened) and inspections conducted more frequently than specified in the priority system on the basis of poor licensee performance. The main consideration in reducing the inspection interval should be evidence of moderate to severe

inspection resources and to reduce regulatory impact on the licensee. This may include more frequent inspections to ensure that inspectors have the opportunity to sufficiently observe licensee operations and increase public confidence by increasing the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees. For example, rather than perform a single, large team, high impact inspection of the license at the normal interval, more frequent inspections may be performed by individuals or smaller teams that specifically focus on higher risk licensee activities.

2800-07 SPECIAL INSPECTION ACTIVITIES

07.01 Expired and Terminated Licenses and Decommissioning Activities. Notification that a license has expired or is being terminated requires prompt action (i.e. within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.

Inspectors should be aware of the need for security and control of radioactive materials at these types of facilities. This may be done by review of the licensee's transfer, disposal, and closeout survey data; by confirmation that an authorized recipient has received the material; and/or by performance of an inspection that may include confirmatory surveys. The inspector should also review records of disposals, burials, and public dose that may be required to be submitted to the DEP on termination or retirement of the license. Such actions would be conducted as soon as appropriate after notification is received.

If an inspection is performed, the inspector should also verify that the licensee is complying with regulations for timely decontamination and decommissioning, and meeting the required schedules for licensee action, as specified in the decommissioning timeliness rule. Specific guidance for performing closeout inspections is outlined in IP 83890.

07.02 Significantly Expanded Programs. During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. A license reviewer may request a near-term onsite inspection for a significant licensing action that was recently completed. Both the inspectors and the reviewers should make the inspection and licensing supervisors aware of the following changes in a licensee's scope of use.

a. Through interviews of licensee staff or observations of licensed activities, the inspector shall determine if:

   1. the licensee has recently increased the types, quantities, and uses of radioactive material;

   2. the license authorizes a physical move of a facility or a new use at a temporary jobsite;

   3. the license authorizes new (i.e., since the previous inspection) satellite facilities where materials will be used or stored;

   4. the licensee has increased the types of uses or disposal (i.e., incineration or

is the basis for the general license under 25 Pa. Code 217.203.

07.04 Temporary Job Site or Field Office Inspections

a. Temporary Job Sites. For a licensee authorized to work at a temporary job site, inspectors shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).

1. During the inspection of a licensee's principal place of business, the inspector should, through discussions with the licensee and review of licensed material utilization records, ascertain if the licensee is working at the temporary job site location(s).

2. The inspector may contact the licensee's customer to schedule the temporary job site inspection. The licensee's customer should be requested not to notify the licensee of the inspection.

3. If an unannounced inspection of the location(s) is not possible, then the inspector should attempt to arrange an announced inspection at the temporary job site(s).

4. If a temporary job site inspection is not performed, a brief note will be written in the inspection records, giving an explanation for the missed temporary job site inspection. In certain cases, the "next inspection date" may indicate a reduced inspection interval. [See Section 06.04]

b. Permanent Field Offices. Each region is responsible for requesting an assist inspection (i.e., an inspection conducted by one region at the request of another region) at each permanent field office to be inspected, if these locations are outside the geographical area of the region. The inspecting region should provide complete documentation and recommend enforcement action to the licensing section, which will distribute the documentation, and take other follow-up actions, as appropriate to the case. [See Section 09.02]

1. If the license authorizes licensed activities to be conducted from two or three permanent facilities (main office plus one or more field offices), only one location must be inspected at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from 4 to 10 permanent facilities (main office plus 3 to 9 field offices) at least 2 locations must be inspected at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from more than 10 permanent facilities (main office plus more than 9 field offices), about 20 percent of the locations should be inspected. Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.

2. If the license does not authorize licensed activities at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field

inspections of major, broad-scope academic or medical licensees, large manufacturers, or in cases where team members from agencies outside the DEP (other than NRC) are involved. [See examples (a) and (d) in this section]

07.06 Abandonment of Licensed Activities. Returned, undeliverable mail to licensees should trigger a prompt follow-up. The follow-up should include a telephone call to the licensee to establish the licensee's physical address. If telephone contact is not established, then an inspector should be sent to the licensee's site. The regional decision of when to send an inspector to a licensee's site should be based on the complexity of the licensed activities, and the types and quantities of licensed material.

07.07 Inspection of Generally Licensed Devices. Routine inspections of general licensees [other than reciprocity] are not normally performed. However, if a specific licensee also possesses generally licensed devices that require registration under 25 Pa. Code 217.143 (and 10 CFR Part 31 incorporated by reference), the inspector should verify the adequacy of the licensee's control and accountability of the devices [See IP 87124, Focus Element 1]. Inspections of general licensees shall also be made to resolve issues such as allegations, incidents, or indications of unsafe practices.

07.08 Reserved.

07.09 Reserved.

2800-08 DOCUMENTATION OF INSPECTION RESULTS

08.01 What Constitutes an Inspection. The following guidance is provided to assist in determining when activities constitute an inspection.

a. An inspection will be considered to have been performed if:

1. the inspection involves a licensee that possesses or has possessed licensed material since the last inspection, including material possessed under a "possession-only license" or that is performing or has performed licensed activities since the last inspection; or

2. the inspection is an initial inspection that has been performed in accordance with Section 05.03.

If it is possible to inspect records or other items according to license conditions or DEP regulations, such activities should be inspected and be recorded as an inspection, whether the radiation safety officer (RSO) is present or not, including those licenses that have expired or are being processed for termination.

08.03 Methods of Documenting Inspection Results. Inspections shall be initially documented by completing inspection records or a narrative report.

a. Inspection results will be documented on Enclosure 5 or in a narrative report as described below, and the region will communicate the inspection findings to the licensee in a formal letter with a Notice of Violation, if appropriate. The inspection records do not have to be typed, but should be legible and should contain:

1. the procedure(s) used;
2. the focus areas examined;
3. the status of follow-up items involving prior enforcement or reported licensee events;
4. sufficient information to support cited violations, non-cited violations, and closed violations identified during a previous inspection;
5. description of completed and anticipated corrective actions to any identified violations; and
6. a succinct description of the scope of the licensee's program.; and,
7. if applicable, a statement that the licensee's reporting to NMMSS was reviewed in accordance with the procedures described in Enclosure 6.

A different inspector should be able to use the inspection records in preparing for a subsequent inspection, and to determine whether corrective actions have been taken.

b. A narrative report is required for all team inspections and actions involving an enforcement conference or escalated enforcement. For escalated cases, the narrative report need address only the areas in which safety concerns and violations are identified (all other areas may be documented using Enclosure 5). All inspection documentation shall be filed in the licensee's docket file. Narrative inspection reports may be used to document other types of inspections at the discretion of regional management.

08.04 Methods of Transmitting Inspection Results. Results of inspections shall be reported to the licensee by regional office letter either with or without a Notice of Violation (NOV) to the licensee.

A letter, signed by regional management (supervisor or higher), shall be used:

1. for repetitive violations;

2. for violations involving willfulness;

3. where a significant or problem is indicated;

4. when an enforcement conference or a management meeting is to be held;

5. where the licensee needs to take extensive corrective action or make

the requirements of other agencies, except those incorporated by reference. However, DEP inspectors may identify concerns that are within another agency's regulatory authority. If such concerns are significant and the licensee demonstrates a pattern of unresponsiveness, the DEP regional office, in coordination with Central Office, should inform the appropriate liaisons within the other agency about the concerns.

Except for regulations incorporated by reference, it is important that all inspectors recognize and understand that they are not to make decisions regarding activities under the purview of other agencies. Thus, in discussing the concerns with the licensee, inspectors are cautioned not to judge whether a given condition is a violation of another agency's rules or regulations, but are to point out concerns to heighten licensee awareness. For example, if an inspector identified concerns for lack of fire protection, then it would be appropriate to encourage the licensee to advise the local fire department of conditions in the facility and to take prompt action to correct the situation. The inspector would also advise the licensee of the inspector's obligation to inform the DEP supervisor who may coordinate the information with OSHA.

In the case of complaints or allegations involving another federal agency's jurisdiction, the inspector should withhold the information from the licensee and elevate the concerns to the attention of DEP regional management while the inspector is still onsite. [see Section 08.02]

2800-11 INPUT INTO DEP TRACKING SYSTEMS

11.01 Input into the Materials Licensing Application Database. Enclosure 1 provides a listing of license program codes with the associated inspection priorities. Enter data promptly into the database at the time a new license is issued. Client, site, facility and inventory records are also created in eFacts. Compliance records are created in eFacts when an inspection has been performed. The compliance record includes as a minimum, the dates for initial inspections of new licensees, the last inspection date, and the next inspection date for licensees already inspected. When changes are made to the next inspection date, regions should enter the data for the correct next inspection date into eFacts and annotate the inspection file.

11.02 Input into the Nuclear Materials Events Database (NMED). Central Office manages NMED for all material-related incidents and events. The regional office is responsible for ensuring that Central Office is notified of all material-related incidents. The regional office shall also forward annotated copies of all documentation regarding a material incident (i.e., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the Central Office.

The regional office is responsible for ensuring that sufficient information is provided for the NMED item to be considered "complete.".

The target for ensuring "complete" NMED records is 70 days from the date the event is reported. The regional office shall provide the information outlined in Enclosure 3 to

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
01100	3	Academic Type A Broad	Radiation Safety Committee (RSC)-approved users;33.13
01110	5	Academic Type B Broad	Radiation Safety Officer (RSO)-approved users; 33.14
01120	5	Academic Type C Broad	Authorized Users specifically named in the license; 33.15
02110	2	Medical Institution Broad	RSC-aporoved users for possession and use of a wide range of radionuclides in medical research, diagnosis, and therapy and research and development.
02120	3	Medical Institution–Written Directive (WD) Required	Used as primary code and may be used with the secondary codes for research and development, as appropriate. Used as secondary code when the license also authorizes certain medical therapy modalities.
02121	5	Medical Institution–WD Not Required	Used as primary code *only* for diagnostic nuclear medicine and diagnostic types of use under 35.1000. Used as secondary code when the license also authorizes certain medical therapy modalities.
02200	3	Medical Private Practice–WD Required	[same remark as 02120]
02201	5	Medical Private Practice–WD Not Required	[same remark as 02121]
02210	3	Eye Applicators Strontium-90 (Sr-90)	Institution or Private Practice
02220	3	Mobile Medical Service–WD Not Required	Use as a primary code if the license authorizes the mobile service *only*. Use as a secondary code if the license authorizes medical use at a central facility (i.e., institution or private practice facility) in addition to the mobile service.
02230	2	High-Dose Rate Remote After loader (HDR)	Use as a primary code.
02231	2	Mobile Medical Service–WD Required	Use as a primary code. Includes mobile HDR and non-HDR modalities under 10 CFR Part 35
02240	2	Medical Therapy–Other Emerging Technology	Medical therapy modalities used under 10 CFR 35.1000, i.e., liquid

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
03122	T[1]	Measuring Systems Analytical Instruments	i.e., x-ray fluorescence analyzers
03123	T	Measuring Systems Gas Chromatographs	Quality control testing of samples from industrial process and environmental conditions.
03124	T	Measuring Systems Other	instrument calibrators, Krypton-85 (Kr-85) leak detectors
03211	2	Manufacturing and Distribution Broad–Type A	RSO-approved users under 10 CFR 33.13
03212	5	Manufacturing and Distribution Broad–Type B	RSO-approved users under10 CFR 33.14
03213	5	Manufacturing and Distribution Broad–Type C	Authorized Users specifically named in the license under 10 CFR 33.15
03214	5	Manufacturing and Distribution Other	Smaller firms that require a more restrictive license.
03218	3	Nuclear Laundry	Cleaning of protective clothing contaminated with radioactive materials.
03219	3	Decontamination Services	Cleaning of scrap materials for authorized release for unrestricted use.
03220	T	Leak Test Service Only	Commercial service organizations provide leak test kits to clients, perform measurement of leak test samples from clients, and issue reports of leak test results.
03221	5	Instrument Calibration Services Only–Source Less Than Or Equal To 100 Curies	Commercial calibration service
03222	5	Instrument Calibration Services Only–Source Greater Than 100 Curies	Commercial calibration service
03225	5	Other Services–Source Less Than Or Equal To 100 Curies	Commercial servicing for industrial gauge, and HDR licensees
03226	2	Other Services–Source Greater Than 100 Curies	Commercial servicing for teletherapy, irradiators , and GSR units containing a total activity in the unit during servicing that is greater than 100 curies.
03231	2	Waste Disposal (Burial)	Commercial and non-commercial

[1] Priority T denotes a telephone contact made by an inspector to evaluate the radiation protection program for Program Codes 03122, 03123, 03124, 03220, 11210, 22130, 22160, and 22161. The telephone contact interval is 5 years.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
			code, except when the license authorizes the PRI *only*.
03320	1	Industrial Radiography Temporary Job Sites	Use as primary code for multiple temporary customer locations
03510	5	Irradiators Self Shielded Less Than Or Equal To 10,000 Curies	Not external beam
03511	5	Irradiators Other Less Than Or Equal To 10,000 Curies	Panoramic (in air or under water) units; includes converted teletherapy units
03520	5	Irradiators Self Shielded Greater Than 10,000 Curies	Not external beam
03521	2	Irradiators - Other Greater than 10,000 curies	Panoramic (in air or under water) units; includes sterilization (mega-curie) units
03610	3	Research and Development Broad–Type A	RSC-approved users under 10 CFR 33.13
03611	5	Research and Development Broad–Type B	RSO-approved users under 10 CFR 33.14
03612	5	Research and Development Broad–Type C	Authorized users specifically named in the license under 10 CFR 33.15
03613	2	Research and Development Broad–Multisite–Multiregional	Multiple sites in multiple regions
03620	5	Research and Development Other	Non-human research subjects
03710	5	Civil Defense	Instrument calibration and training
03800	3	Byproduct Material Possession Only - Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized
03810	3	Byproduct Material Standby - No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
22120	5	SNM Plutonium - Sealed Neutron Sources, Less than 200 Grams	Plutonium-beryllium howitzer for instrument calibration, teaching and demonstration purposes, and industrial applications
22130	T	Power Sources with Byproduct and/or Special Nuclear Material	Heat or power generators for remote locations
22140	5	Special Nuclear Material Plutonium - Sealed Sources in Devices	Gauges
22150	5	Special Nuclear Material Plutonium - Sealed Sources Less than a Critical Mass	Less than 200 grams, total, for biological and chemical testing and instrument calibration
22151	5	Special Nuclear Material, U-235 and/or U-233 Sealed Sources, Less than a Critical Mass	Less than 350 grams U-235 and/or less than 300 grams U-233 for biological and chemical testing and instrument calibration
22160	T	Pacemaker–Byproduct, and/or Special Nuclear Material - Medical Institution	Surgical implantation, follow up, recovery, and disposal of devices
22161	T	Pacemaker–Byproduct, and/or Special Nuclear Material - Individual	Possession of a surgically implanted device by the recipient while in the United States
22162	2	Pacemaker–Byproduct and/or Special Nuclear Material - Manufacturing and Distribution	
22170	5	Special Nuclear Material General License Distribution (70.39)	Includes calibration or reference sources authorized under 10 CFR 70.19
22200	D	Decommissioning of Other SNM Facilities - Less than Critical Mass	(See MC 2602) D&D may have been authorized according to an approved plan under 10 CFR 70.38
23300	2	SNM Possession Only (Non-Fuel)-Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized
23310	2	SNM Standby (Non-Fuel)-No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized

ENCLOSURE 2

TELEPHONE CONTACT PROCEDURES FOR PRIORITY T LICENSEES

1. PROGRAM OBJECTIVES: The Central Office developed telephone contact procedures to maintain safety for materials possessed by certain licensees (Priority T) after the initial inspection was completed and the inspector determined that the licensee had satisfactorily implemented the radiation protection program. Thereafter, an inspector will interview the Priority T licensee at 5-YEAR intervals for the duration of the license.

2. PROCEDURES

   a. Select a Priority T licensee to interview by telephone [see Section 05.05].

   b. Obtain the license file and identify the licensee's point of contact and review pertinent details of the license that will be needed to evaluate the licensee's responses to the interview questionnaire. (Exhibit 1).

   c. Telephone the licensee and complete each item of Exhibit 1, as appropriate for the type of use authorized by the license. If a question is not applicable for the type of use, then indicate "N.A." for the answer.

   d. The inspector should promptly notify their supervisor if the licensee describes any significant problem. The supervisor should determine whether an inspection of the facility or a letter transmitting regulatory concerns is needed. If an inspection is warranted, the inspector should note that decision on Exhibit 1 and provide the completed questionnaire and license file to the supervisor for further action. Use Exhibit 2, "Standard Response to Licensees Contacted by Telephone (Concerns, Inspection to Follow)," to notify the licensee that a follow up inspection may be scheduled in the near future. Following is a list of problems which may warrant an onsite inspection.

      1. licensee is unaware of licensed material or DEP regulations for possession, use, transfer, and disposal

      2. change in ownership or bankruptcy proceedings

      3. a qualified radiation safety officer or authorized user was not routinely involved

      4. unsecured or unshielded material

      5. doses in excess of 10 CFR Part 20 limits

      6. excessive radiation levels or leaking sources

      7. lost, stolen, or missing licensed material

      8. non-routine event threatens safe, secure storage (i.e., special maintenance or

EXHIBIT 1: TELEPHONE CONTACT QUESTIONNAIRE

Instructions: Complete this questionnaire as per the program objectives and procedures for Enclosure 2.

Name and title of Interviewer Signature of Interviewer	
Date of this Interview Date of Previous Interview	
QUESTIONS	**ANSWERS**
Licensee Name, Address, and URL	
Licensee's Point of Contact (Name, Address, Phone and FAX Numbers, and URL)	
License Number Docket Number	
1. Name and Title of person responsible for radiation safety program:	
2. Describe how you prevent: (a) use by unauthorized personnel and (b) loss or theft.	
3. Describe how you maintain shielding, restrict access, and control contamination from unsealed material to prevent individuals from becoming exposed to radiation.	
4. Describe how you determine radiation doses to workers and members of the public from licensed activities. What was the maximum dose received since the last DEP or NRC telephone contact or inspection?	
5. Describe radiation area surveys around licensed activities. What survey instrument (SI) was used? SI's last calibration date? What were the typical radiation levels and at what distance?	
6. Describe leak testing of the sealed source(s). How often and who analyzed the leak test samples? What were the most recent results?	

EXHIBIT 3
STANDARD RESPONSE TO LICENSEES CONTACTED BY TELEPHONE
(NO CONCERNS / VIOLATIONS)

Licensee Name [License No.]
Address

ATTENTION: [Licensee Point of Contact, Title]

SUBJECT: TELEPHONE INTERVIEW TO EVALUATE THE RADIATION SAFETY PROGRAM

Sir or Madam:

This refers to the interview by telephone on [date]. The interview was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Department of Environmental Protection rules and regulations and with the conditions of your license. No regulatory concerns were identified.

If you have any questions about this matter, please contact me at [phone, fax, email address].

Sincerely,

[Inspector Name, Title]

ENCLOSURE 3
INFORMATION FOR THE NUCLEAR MATERIALS EVENTS DATABASE (NMED)

The regional office shall forward copies of all documentation regarding a material incident (i.e., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the Central Office.

The regional office is responsible for ensuring that sufficient information is provided for the NMED item to be considered "complete." The basic information along with the additional specific information for certain types of events, outlined below, constitutes the "complete" record.

The target for ensuring "complete" NMED records is 70 days from the date the event is reported. The information identified below must be provided to classify a record as "complete." If there is a reason that required information can not be obtained, that reason should be forwarded to the Central Office.

Basic Information:

1. Essential Details
   a. narrative event description
   b. report identification number
   c. event date and notification date
   d. licensee/reporting party information (name, license number, and address)
   e. site of event
   f. whether the event is DEP reportable and the applicable reporting requirement
   g. cause and corrective actions
   h. number of persons involved, consequences
   I. notifications: local police, FBI, other States, as needed
   j. identify any possible generic safety concerns/potential for others to experience the same event
2. Source/Radioactive Material:
   a. isotope and activity
   b. manufacturer
   c. model and serial number
3. Device/Associated Equipment:
   a. manufacturer
   b. model and serial number

ENCLOSURE 4

INSPECTION MANUAL CHAPTERS AND INSPECTION PROCEDURES

MC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
	MATERIALS SAFETY PROGRAMS	
MC1220	"Processing of DEP Form 241,'Reciprocity - Report of Proposed Activities in Pennsylvania, in Areas of Department Jurisdiction,' and Inspection of Reciprocity Licensees Operating Under 25 PA Code Chapter 217 Subchapter J"	N
MC2815	"Construction and Pre-Operational Inspection of Panoramic, Wet-Source Storage Gamma Irradiators"	N
IP 87121	"Industrial Radiography Programs"	R
IP 87122	"Irradiator Programs"	R
IP 87123	"Well Logging Programs"	R
IP 87124	"Fixed and Portable Gauge Programs"	R
IP 87125	"Materials Processor/Manufacturer Programs"	R
IP 87126	"Industrial/Academic/Research Programs"	R
IP 87127	"Radiopharmacy Programs"	R
IP 87130	"Nuclear Medicine Programs–Written Directive Not Required"	R
IP 87131	"Nuclear Medicine Programs–Written Directive Required"	R
IP 87132	"Brachytherapy Programs"	R
IP 87133	"Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs"	R
IP 87134	"Medical Broad-Scope Programs"	R
	CONDUCT OF INSPECTIONS	
MC 0300	"Announced and Unannounced Inspections"	R

MC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
IP 87104	"Decommissioning Inspection Procedures for Materials Licenses"	N
	RADIATION PROTECTION	
IP 83822	"Radiation Protection"	R
IP 87102	"Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)"	R
	TRANSPORTATION	
MC 1330	"Response to Transportation Accidents Involving Radioactive Materials"	N
IP 86740	"Inspection of Transportation Activities"	R
	REPORTS/COMMUNICATIONS/FOLLOW-UP	
MC 0610	"Radioactive Material Safety and Safeguards Inspection Reports"	R
MC 0620	"Inspection Documents and Records"	R
MC 1120	"Preliminary Notifications"	N
MC 1232	"Collection Preparation and Shipment of Independent Measurement Samples"	N
IP 92701	""Follow-up"	R

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

2. SCOPE OF INSPECTION:
(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure(s) Used:

Focus Areas Evaluated:

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

4. VIOLATIONS, Non Cited Violations (NCV's), AND OTHER SAFETY ISSUES:
(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

5. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

-END-

ENCLOSURE 6

Reserved